

PATENT**REMARKS****Preliminary Matter**

In response to the objection of claims 8 and 13 because of informalities, the following amendments have been made: claim 8, line 2, "until" has been replaced with --unit--; and claim 13, line 1, "13" has been replaced with --15--. Accordingly, it is respectfully submitted that the objection to claims 8 and 13 be withdrawn.

Furthermore, claim 6 has been amended to correct an inadvertent typographical error. In particular, in line 10, "an" has been replaced with --a--. Acceptance of the amendment is respectfully requested.

Rejection of Claims 1-8 and 11-14 under 35 U.S.C. §102(e) as being anticipated by Bradley et al.

Claim 6 of the present application recites a system comprising a backup pulse unit delivering backup pulses to the heart upon detection of loss of capture of a primary pacing pulse. The capture detection unit detects loss of capture of backup pacing pulses. The system further comprises a capture-based tachycardia detection unit detecting a tachycardia based upon loss of capture of backup pacing pulses as detected by the capture detection unit.

The Bradley et al. reference is directed to providing capture verification during overdrive pacing. In accordance with the Bradley et al. reference, in an attempt to avoid loss of capture during overdrive pacing, conventional devices typically set the magnitude of the overdrive pulses to be quite high so as to assure that the overdrive pulses are captured. The need to apply overdrive pacing pulses with high pulse magnitude operates to deplete the power supply of the implantable cardiac stimulation device. The Bradley et al. reference addresses this problem by providing an overdrive pacing technique that permits a reduction in the average magnitude of overdrive pacing pulses while still achieving adequate capture. A control unit control unit controls a pulse generator to overdrive pace the heart at an overdrive pacing rate with each pulse set to a standard pacing pulse magnitude. The control unit performs capture

PATENT

verification on each overdrive pacing pulse. If a pulse fails to evoke capture, the pulse generator is controlled to generate a backup pulse having a pulse magnitude greater than a standard overdrive pulse magnitude for delivery to heart tissue. By providing capture verification of overdrive pacing pulses, the pulse magnitude of each overdrive pulse can be reduced as compared with systems wherein capture verification of overdrive pulses is not performed and wherein, instead, overdrive pulses are merely set to a high pulse magnitude in an attempt to ensure capture.

In accordance with another aspect of the invention of the Bradley et al. reference, standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search. The threshold detection search may be performed, for example, whenever two consecutive overdrive pulses fail to evoke capture within a single dwell time. When two consecutive loss of captures are detected, the overdrive pulse magnitude is incrementally increased until two consecutive captures are detected. A safety margin is added to the resulting pulse magnitude to yield a new standard overdrive pulse magnitude. A backup pulse is issued after every beat that is not captured during the capture threshold assessment. By providing for automatic capture threshold detection searches, the standard pulse magnitude of the overdrive pulses can be kept as low as possible while still ensuring that substantially all overdrive pulses are properly captured.

The Bradley et al. reference does not disclose or suggest a capture detection unit that detects loss of capture of backup pacing pulses. As stated previously, if any of the overdrive pacing pulses is not captured by the atria, a backup pacing pulse is delivered 40 ms after the pulse that failed to evoke capture. If the loss of capture is a first loss of capture, processing continues for further overdrive pacing. However, upon detection of a second consecutive loss of capture during the dwell time, the overdrive unit performs an automatic capture threshold detection search to set a new capture threshold and a new pulse magnitude. Nowhere during this process does the device detect loss of capture of backup pacing pulses. Determination of a loss of capture is directed to the overdrive pacing pulses.

PATENT

It is also noted that none of the remaining cited references (Andersson et al., Obel et al., Zhu et al., Bornzin et al., Lu, and Olson et al.) disclose or suggest a capture detection unit that detects loss of capture of backup pacing pulses. These references are directed to a device that detects loss of capture of a primary pacing pulse.

Furthermore, the Bradley et al. reference does not inherently disclose or suggest a capture-based tachycardia detection unit detecting a tachycardia based upon loss of capture of backup pacing pulses as detected by a capture detection unit. In accordance with the present application, antitachycardia pacing (ATP) therapy is most effective if applied early during the tachycardia. Unfortunately, conventional techniques (such as disclosed in the Bradley et al. reference) for detecting the onset of a tachycardia do not detect the tachycardia as promptly as would be desired. One technique for detecting an atrial tachycardia is to monitor the atrial rate and initiate ATP if the heart rate exceeds a certain threshold. It may take a fair number of cardiac cycles before the stimulation device can reliably detect a high atrial rate and, in particular, distinguish a high heart rate from a temporary shortening of an atrial heart rate interval caused by a premature beat such as a premature atrial contraction. Another known method is to differentiate pathologic rhythms from normal physiologic rhythms by analyzing heart rate stability. Again, a fair number of cycles may be required before the stimulation device can reliably distinguish a change in heart rate stability caused by a tachycardia from one caused by premature beats or other transient factors. Thus, conventional tachycardia detection techniques do not always detect tachycardia as quickly as desired, resulting in a reduced likelihood that subsequent therapy will be successful. The present application provides improved techniques for promptly and reliably detecting tachycardia, wherein tachycardia is detected based on a loss of capture of a backup pulse.

In accordance with the Bradley et al. reference, the device utilizes atrial and ventricular sensing circuits to detect arrhythmia in a conventional manner. The timing intervals between sensed events (e.g., P-waves, R-waves, and depolarization signals associated with fibrillation) are then classified by a microcontroller by comparing them

PATENT

to a predefined rate zone limit (i.e., bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones) and various other characteristics (e.g., sudden onset, stability, physiologic sensors, and morphology) in order to determine the type of remedial therapy that is needed.

Accordingly, it is respectfully submitted that claim 6 is in condition for allowance. Claims 2-5 and 7-10 depend from claim 6 and are similarly patentable.

Rejection of Claims 15 and 18-20 over Bradley et al. in view of Olson et al.

Without addressing the merits of the rejection of claim 15 and 18-20, in accordance with the American Inventors Protection Act, the Bradley et al. reference does not qualify as prior art for a rejection under 35 U.S.C. §103(a) via 35 U.S.C. §102(e) because the present application has been filed on or after November 29, 1999 and the subject matter of the Bradley et al. reference and claims 15 and 18-20 were, at the time the invention was made, subject to an obligation of assignment to the same organization (see section entitled "Obligation of Assignment to the Same Organization"). Accordingly, the Bradley et al. reference no longer qualifies as prior art under 35 USC §103(a) via 35 USC §102(e) and it is respectfully submitted that claims 15 and 18-20 are in condition for allowance. Claims 12-14, 16, and 17 depend from claim 15 and are similarly patentable.

Obligation of Assignment to the Same Organization

Ronald Tamura, an attorney of record for the present application, states that Application Serial Number 10/657,840 and U.S. Patent Application Publication No. 2003/0208241 were, at the time the invention of Application Serial Number 10/657,840 was made, owned by Pacesetter, Inc. or subject to an obligation of assignment to Pacesetter, Inc.

PATENT**CONCLUSION**

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

6/1/06
Date

Ronald S. Tamura

Ronald S. Tamura, Reg. No. 43,179
Patent Attorney for Applicant
818-493-3157

CUSTOMER NUMBER: 36802